Attorney Docket No. 2300-19199 (PP19199.002)   **PATENT**

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Date of Deposit: *September 8, 2003*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of   ARCANGEL et al.

Serial No.:   Examiner: Unassigned

Confirmation No.:   Art Unit: Unassigned

Filed: On even date herewith

For: HCV ASSAY

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97(b)

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56,

Applicant(s) hereby submits the following information in conformance with 37 C.F.R.

§§1.97 and 1.98.

[X]   Pursuant to 37 C.F.R. §1.98, a copy of each document cited in the attached
        Form PTO-1449 is enclosed.

[]   No copies of the publications listed on the attached Form PTO-1449 are
        being provided pursuant to 37 C.F.R. §1.98(d) because the publications
        were previously cited by or submitted to the Office in prior Application
        Serial No. ___ to which the above-identified application claims priority
        under 35 U.S.C. §120.

[]   Publication(s) _____ listed on the attached Form PTO-1449 were cited in
        a foreign search or examination report corresponding to ____ application
        serial no. _____ and mailed on _____.

[]   Enclosed is a copy of a non-English publication(s) ___. Pursuant to §609
        of the M.P.E.P., Applicant submits the attached foreign search or
        examination report, which cites such non-English language publication(s).

[]   Enclosed is a copy of a non-English publication(s) ___. English language publication ___ (copy enclosed) claims priority from this non-English publication.

[]   Enclosed is an explanation of non-English publication(s) ___ for which an English translation is not available.

[]   Enclosed is an English translation of non-English publication(s) ___cited in the attached Form PTO-1449.

[]   Enclosed is a copy of pending patent Application Serial No. ___.

This Information Disclosure Statement is filed with the herein application.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO-1449 to the undersigned.

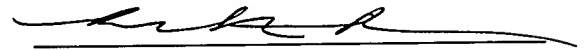Please direct all further written communications in this application to:

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Dated: ___9/8/03___   Respectfully submitted,

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FORM PTO-1449 (Modified)
LIST OF PATENTS AND PUBLICATIONS
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(Use several sheets if necessary)
Sheet _1_ of _4_

In the Application of ARCANGEL et al.

Serial No.:   Art Unit: Unassigned

Filed: On even date☐   Examiner: Unassigned

Title: HCV ASSAY

U.S. PATENT DOCUMENTS

Exam.Init.	Ref. Desig.	Document No.	Date	Name	Class	Sub Class	Filing Date
	A1	5,350,671	September 27, 1994	Houghton et al.			
	A2	5,712,087	January 27, 1998	Houghton et al.			
	A3	5,843,752	December 1, 1998	Dasmahapatra et al.			
	A4	5,871,904	February 16, 1999	Kashiwakuma et al.			
	A5	5,990,276	November 23, 1999	Zhang et al.			
	A6	6,171,782	January 9, 2001	Houghton et al.			

FOREIGN PATENT DOCUMENTS

Exam. Init.	Ref. Desig.	Document No.	Publication Date	Country or Patent Office	Class	Sub Class	Translation YES	NO
	B1	WO 93/00365	January 7, 1993	PCT				
	B2	WO 94/01778	January 20, 1994	PCT				
	B3	WO 97/44469	November 27, 1997	PCT				

Examiner: Date Considered:

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Title: HCV ASSAY

	B4	318,216 ✓	May 31, 1989	EPO				
	B5	388,232 ✓	September 19, 1990	EPO				
	B6	0450931B1 ✓	October 9, 1991	EPO				
	B7	0472207A2	February 26, 1992	EPO				

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Exam. Init.	Ref. Desig.	Description	
	C1	BELD et al., "Evaluation of automated RNA-extraction technology and a qualitative HCV assay for sensitivity and detection of HCV RNA in pool-screening systems," *Transfusion* 40:575-579, 2000	✓
	C2	Chen et al., "Human and murine antibody recognition is focused on the ATPase/helicase domain, but not the protease domain of the hepatitis C virus non-structural 3 protein," *Hepatology* 28:219-224, 1998	✓
	C3	Chien et al., "Diagnosis of Hepatitis C Virus (HCV) Infection Using an Immunodominant Chimeric Polyprotein to Capture Circulating Antibodies: Reevaluation of the Role of HCV in Liver Disease," *Proc. Natl. Acad. Sci. U.S.A.* 89:10011-10015 (1992)	✓
	C4	Chien et al., "Use of Recombinant HCV Antigen in the Serodiagnosis of Hepatitis C Virus Infection: Significant Improvement in HCV Antibody Detection as Compared with the First Generation HCV C100-3 ELISA and the Synthetic Peptide EIA Tests," *Jorunal of Gastroenterology Hepatology* 8:S33-39 (1993)	✓

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	C5	Chien et al., "Distinct subtypes of hepatitis C virus defined by antibodies directed to the putative core, NS4, and NS5 region polypeptides," *Virol. Hepatitis and Liver Disease*:320-324, 1994	⊮
	C6	Choo et al., "Isolation of a cDNA Clone Derived from a Blood-Borne Non-A, Non-B Viral Hepatits Genome," *Science* 244:359-362 (1989)	⊮
	C7	Choo et al., "Hepatitis C Virus: The Major Causative Agent of Viral Non-A, Non-B Hepatitis," *British Medical Bulletin* 46(2):423-441 (1990)	⊮
	C8	Cruse et al., Illustrated Dictionary of Immunology, CRC Press, Boca Raton FL, 1995, p76	⊮
	C9	Ebeling et al., "Recombinant Immunoblot Assay for Hepatitis C Virus Antibody as Predictor of Infectivity," *Lancet* 335:982-983 (1990)	⊮
	C10	Houghton et al., "Molecular Biology of the Hepatitis C Viruses: Implications for Diagnos, Development and Control of Viral Disease," *Hepatology* 14:381-388 (1991)	⊮
	C11	Kotwal et al., "Detection of acute hepatitis C virus infection by ELISA using a synthetic peptide comprising a structural epitope," *Proc. Natl. Acad. Sci. USA* 89:4486-4489, 1992	⊮
	C12	Kuo et al.,"An Assay for Circulating Antibodies to a Major Etiologic Virus of Human Non-A, Non-B Hepatitis," *Science* 244:362-364 (1989)	⊮
	C13	Pereboeva et al., "Hepatitis C Epitopes From Phage-Displayed cDNA Libraries and Improved Diagnosis with a Chimeric Antigen," *J. Medical Virology* 60:144-151, 2000	⊮
	C14	van der Poel et al., "Infectivity of Blood Seropositive for Hepatitis C Virus Antibodies," *Lancet* 335:558-560 (1990)	⊮

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Exam. Init.	Ref. Desig.	Description
	C15	Van der Poel et al., "Confirmation of hepatitis C virus infection by new four-antigen recombinant immunoblot assay," *Lancet* 337:317-319, 1991
	C16	Yao et al., "Molecular views of viral polyprotein processing revealed by the crystal structure of the hepatitis C virus bifunctional protease-helicase," Structure 7(11):1353-1363, 1999

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